K053304

DEC 3 0 2005

EXHIBIT 2
510K Summary

Cardiocom
1260 Park Road
Chanhassen, MN 55317
Toll-Free: 888-243-8881
Tel: 952-474-4149
Fax: 952-474-4372
Contact: Daniel Cosentino, President
Date: November 19, 2005

1. **Identification of the device**
Proprietary-Trade Name: Cardiocom Commander III Non-Invasive Automated Blood Pressure Monitor
Classification Name: DXN, SYSTEM, MEASUREMENT, BLOOD-PRESSURE, NON-INVASIVE,
Common/Usual Name: Noninvasive Blood Pressure Measurement System

2. **Equivalent legally marketed devices**
This product is similar in function and design to predicate K982481 A&D Medical UA-767PC Digital Blood Pressure Monitor

3. **Indications for Use (intended use).** The Commander III device is for use by patients to collect and transmit general health questions and patient vital sign data (such as weight, blood pressure, glucose, pulse oximetry, peak flow) between the patient, typically at home, and a health care professional at a remote site.
Contraindications, Precautions and Warnings: The Commander III device makes no interpretation, evaluation, medical judgments or recommendations for treatment. Clinical judgment and experience are required to check and interpret the information transmitted. The Commander III is not intended as a substitute for medical care..

4. **Description of the Device**. Commander III is similar to a simple personal computer with a modem that stores and transmits data. Commander III connects to a user's telephone line at home. It has a display that asks health related questions to which the user can respond 'Yes', 'No', or select from a list. It also has inputs for devices such as weight scales, blood pressure meters, glucometers, peak flow meters and pulse oximeters. These devices download data through a RS232 connection. The functionality of these devices has not been modified; they are used as supplied from the manufacturer.

5. **Safety and Effectiveness, comparison to predicate device**
The results of bench, laboratory, and clinical testing indicates that the new device is as safe and effective as the predicate device.

6. Comparison matrix – new vs. Predicate device

Designation	K982481 A&D Medical UA-767PC Digital Blood Pressure Monitor	Commander III
Operating Principle	Oscillometric automated blood pressure monitoring	SAME
Indications	The UA-767PC is designed to be used by end users who are eighteen (18) years and older at home and doctor/nurse office to monitor their blood pressure (systolic and diastolic) and pulse rate. At the end of each measurement, the results will be stored in the UA-767PC memory. UA-767PC through its communications port can also transfer the measurements stored in memory to other electronic devices, such as a PC, a modem, or a printer.	The Commander III device is for use by patients to collect and transmit general health questions and patient vital sign data (such as weight, blood pressure, glucose, pulse oximetry, peak flow) between the patient, typically at home, and a health care professional at a remote site. Contraindications, Precautions and Warnings: The Commander III device makes no interpretation, evaluation, medical judgments or recommendations for treatment. Clinical judgment and experience are required to check and interpret the information transmitted. The Commander III is not intended as a substitute for medical care
Display	LCD: Systolic, Diastolic, Pulse	SAME
Controls	Start, pressure select	Yes, No, Up-arrow, Down-arrow, Four "selection buttons"
Power supply	4-AA alkaline batteries	AC Adapter only
External dimensions	2.7" tall 4.4" deep 6.5" wide	2.7" tall 6.8" deep 8.9" wide
Memory	126 measurements	200 measurements. Last measurement is sent over the phone line.
Weight	0.32 kg without batteries	0.8kg without Blood Pressure cuff
Cuff Arm Circumference Range	5.1 inches -17.7 inches (small, medium, large cuff sizes)	7 inches-16.5 inches (small, medium, large cuff sizes)
OTC or prescription	OTC	Prescription
Standard	ANSI/AAMI SP10: 1992+A1	SAME
Electrical Safety	UL/IEC 60601-1	UL/IEC 60601-1
Electromagnetic compatibility	IEC 60601-1-2	IEC 60601-1-2
Patient Contact Materials	Nylon Cuff	SAME
Construction	Electronic printed circuit boards inside an ABS enclosure	Electronic printed circuit boards inside an ABS enclosure

Designation	K982481 A&D Medical UA-767PC Digital Blood Pressure Monitor	Commander III
Description	This home blood pressure monitor communicates with your information hub through a serial communication cable and port. Real-time communication is achieved by sending the blood pressure measurement to the information hub immediately. The UA-767PC can also operate in a batch-mode to send up to 126 measurements with time and date in a single request command. System integrators can provide units to remotely located patients enabling them to monitor their blood pressure at home. Combine this blood pressure monitor and the LifeSource™ UC-321 personal scale and you have a foundation for a complete telemonitoring system.	The Commander III device is for use by patients to collect and transmit general health questions and the following patient vital signs data: Non-invasive blood pressure measurement, Non-invasive blood oxygen saturation measurement using pulse oximetry, In vitro diagnostic quantitative measurement of glucose in fresh capillary whole blood, Non-invasive measurement of lung peak flow, and Patient weight using a stand-on electronic scale. The results of these measurements are transmitted to a computer monitoring station in a clinical setting via common telephone lines from the patient's home setting. For sale by or on the order of a physician.
Communication capability	Serial RS-232 with PC	Multiple serial RS-232 ports and telephone modem Part 68 approved
Measurement Range	Pressure: 20 mmHg to 280 mmHg; Pulse: 40 to 200 pulses/minute	SAME (from AAMI)
Accuracy	Pressure: ±3 mmHg or ±2%, whichever is greater; Pulse: ±5%	SAME (from AAMI)
Pressurization	Automatic, using micropump	Automatic
Operating Environment	50° - 104° F (10° to 40° C)	SAME (from AAMI)

7. Conclusion

After analyzing bench, test laboratory, and clinical testing data, it is the conclusion of Cardiocom that the Cardiocom Commander III is as safe and effective as the predicate device, has essentially no significant technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 0 2005

Cardiocom LLC
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K053304
Trade Name: Cardiocom Commander III
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: December 12, 2005
Received: December 13, 2005

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) _____

Device Name: Cardiocom Commander III

Indications For Use:

The Commander III device is for use by patients to collect and transmit general health questions and patient vital sign data (such as weight, blood pressure, glucose, pulse oximetry, peak flow) between the patient, typically at home, and a health care professional at a remote site.

Contraindications, Precautions and Warnings:
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Prescription Use __X__ AND/OR Over-The-Counter Use _____.
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K053304